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**Walk, Talk 'n Listen**

**Consent form**

**NCT 02662192**



Participant #: \_\_\_\_\_ Date: \_\_\_\_\_

## **“Consent Form”**

## **Walk, Talk ‘n Listen**

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### ***Why should you take part in this study?***

Over one half of older Canadian adults have hearing loss. Hearing loss can cause feelings of social isolation and loneliness, anxiety, stress and frustration. All these feelings can be a negative or bad influence on optimal health and wellness. Many seniors with hearing loss have said they would like a program to help them communicate and be able to listen better, feel less stressed in social situations and be provided with health and nutrition education, as well as opportunities to be more physically active.

The purpose of this study is to provide health education, communication and listening support (called auditory rehabilitation) along with social and physical activity opportunities in a hearing-loss friendly environment. Auditory rehabilitation can help both those with and without hearing aids who are struggling with hearing loss. Even if you don't have hearing aids but have discovered that you have a hearing loss, auditory rehabilitation can give you strategies to improve listening and increase your communication effectiveness and comfort. This study will teach us about the benefits of such programs on the health and well being of older adults with hearing loss in the interior of BC.

You are being invited to take part in this research study because you are 65 years or older, have hearing loss, do not suffer from depression or dementia, and might be at risk for loneliness, isolation and/or less than optimal health and wellness.

***What happens if you say, “Yes, I want to be in the study”? What happens to you in the study? How is the study done?***

There are 2 steps to determine if you are eligible to participate in this study:

Step 1 – phone call will take 5-15 minutes: You will be contacted by our project coordinator and asked several

questions:

- Do you have difficulty hearing when conversing with another person in a noisy environment?
- Can you walk unaided (without a walker or use of a wheel chair)?
- Are healthy enough to participate in a physical activity program without worsening any existing health problems?
- Are you physically active < 150 minutes per week?
- Have you **NOT** been involved in any organized exercise program for at least 6 months?
- Are you available and willing to attend at least 80% of the sessions for the 12-week study?

If you answered “yes” to these questions above, then you will be invited to attend a session at the study site:

Step 2 – Will take about 2-4 hours and will be in person (YMCA Okanagan in Rutland or the H2O Centre in Okanagan Mission): At this session, we will give you some forms with questions to answer and then conduct some fitness testing:

- Forms: We will ask several questions about you (your age, where you live, your household income, physical activity habits, your hearing, your physical health, your mental health and reasoning, whether you have had any falls in the last 3 months and whether you suffer from social isolation and/or loneliness). You will also be asked to fill out a special questionnaire to determine whether it is safe for you to exercise. Based on your answers to this questionnaire, you may need to obtain a letter signed by your doctor indicating that it is safe for you to participate in the study.
- Fitness Testing: This includes how many times you can go from a sitting to a standing position in 30 seconds, from a seated position how fast you can walk 10 meters and return, and how fast you normally walk, a balance test, and how well you can sit and reach for your knees and your blood pressure.

If the questionnaires and (if needed, the doctor’s letter) and the fitness testing indicate that you qualify to enter the study, you will then be randomized (like the flip of a coin) to one group:

- GAR-WTL group: The 10-week Group Auditory Rehabilitation and health education/ physical activity and walking group. The 2-hour GAR-WTL sessions will occur twice a week. The first hour will be the GAR session or a health education session and the second hour, an exercise and pedometer-based walking session. The exercise sessions will be led by certified YMCA fitness instructors and students. Specific health topics explored during the program will be chosen by you and the other participants.

OR

- GAR-only group: The 10 week Group Auditory Rehabilitation only. The 1-hour GAR-only sessions will occur once a week. They will be led by our research team. Together, you will discuss the challenges and stresses of having hearing loss and support each other in learning how to cope better with hearing loss. In addition, you will obtain special training to help you communicate and listen better (for example lip-reading and non-verbal body language). You will also learn practical strategies to reduce hearing related stress and embarrassment in group settings.

No matter which group you are in, you will receive Group Auditory Rehabilitation (GAR). Even if you are in the GAR-only group, you will not miss out on the exercise program, because you will be invited to take part in the

exercise program at the end of the study.

Because this study was designed with input from older adults with hearing loss, we have taken special care to provide a hearing friendly environment. Both the GAR-WTL and GAR sessions of the study will take place in small rooms equipped with an FM amplification system to help you hear better. All groups will include only 9 other participants who also have hearing loss. Free transportation may be arranged for participants without transportation.

At the end of the study you will be asked if you liked the program and what suggestions you might have to improve it. You will also complete similar questionnaires and fitness testing procedures that you did at the beginning of the study. This is done to determine your baseline or starting point and compare it with your end of program changes, as part of an evaluation of the benefits and effectiveness of our program. If you were assigned to the GAR only group, you can start the exercise part of the program right after completing the final set of questionnaires and fitness testing. You will be asked to repeat these same questionnaires and fitness testing again, 10 weeks later at the end of the exercise part of the program.

Including the personal time you spend on your walking program at home, and the 1-2 weekly program sessions, you will spend about 75-120 hours total on program activities over the 3-month period.

### ***How will you find out about the study results?***

We will mail you a one-page summary of the overall results of the study. The results of the study will be available to you through media releases, community newsletters, local newspapers, project updates, posters, brochures, key message summary sheets delivered to the program community center, public forum presentations (live, for example mini-medical school public forums), discussion groups at local community centers and agencies such as the Westside Health Network Society, the Salvation Army, The Society of Hope, The Westside Lions.

### ***Is there any way being in this study could be bad for you?***

We do not think that there is any physical risk to you beyond what might be encountered in the course of active daily life. However, some of the questions we ask may upset you. Please let one of the study staff know if you have any concerns. Some of the questions we ask may seem sensitive or personal. You do not have to answer any question if you do not want to.

### ***What are the benefits of participating?***

You may gain new friends and a larger social circle. You may feel less lonely and isolated. You may feel less stressed about your hearing loss and you may find that you are more comfortable with new skills to cope in a group or social setting. You may increase your knowledge about healthy eating, physical activity and other topics that you are interested in learning about. You may become more physically fit and strong.

### ***How will your privacy be maintained?***

We encourage participants in our group programs and in small group discussions not to discuss the content of the discussions that might include private participant comments to people outside the group; however, we cannot control what participants do with the information discussed. Your confidentiality will be respected. Information about your identity will not be released without your consent unless required by law. All documents, computers or computer data will be identified only by code number and kept in a locked filing cabinet, in a locked office on a

locked floor. You will not be identified by name in any reports of the completed study.

***Will you be paid for your time/ taking part in this research study?***

We will not pay you for the time you take to be in this study. Transportation may be available if you do not have access to or cannot afford transportation.

***Who can you contact if you have questions about the study?***

If you have any questions or concerns about what we are asking of you, please contact the study leader or one of the study staff. The names and telephone numbers are listed at the top of the first page of this form.

***Who can you contact if you have complaints or concerns about the study?***

“If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Services at 1-877-822-8598 or the UBC Okanagan Research Services Office at 250-807-8832. It is also possible to contact the Research Participant Complaint Line by email (RSIL@ors.ubc.ca).”

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your [for example, employment, class standing, access to further services from the community centre, day care, etc.].

Do you agree to be contacted by one of our research team around 3-6 months after the finish of the program? We will only ask you a few questions about how you have been doing since the program ended and if you have had any falls.

Please circle:                      yes                                      no

If yes, may we contact you by phone?

Please provide the phone number you would like us to call: \_\_\_\_\_

- Your signature below indicates that you have received a copy of this consent form for your own records.
- Your signature indicates that you consent to participate in this study.

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Participant Signature

Date

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Printed Name of the Participant signing above